AbbVie Inc.

PMOS Protocol P15-692

Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 Months on Adalimumab Treatment (HOPE study)

Amendment 1

07 February 2017

The purpose of this Amendment is to:

- Extend Enrollment Period
- Add interim analysis
- Incorporate Administrative Change 1

Section 4.0, Abstract

Previously read:

Milestones: Start of data collection: Planned Q1 2016 End of data collection: Planned Q3 2017 Final Report of Study Results: Planned Q3 2018

Has been changed to read:

Milestones: Start of data collection: Planned Q1 2016 End of data collection: Planned Q1 2018 Final Report of Study Results: Planned Q1 2019

Section 6.0, Milestones

Previously read:

Major study milestones and their planned dates are as follows:

Start of Data Collection:	Planned Q1 2016
End of Data Collection:	Planned Q3 2017
Final Report of Study Results:	Planned Q3 2018

Has been changed to read:

Major study milestones and their planned dates are as follows:

Start of Data Collection:	Planned Q1 2016
End of Data Collection:	Planned Q1 2018
Final Report of Study Results:	Planned Q1 2019

Section 9.7, Data Analysis

Previously read:

All statistical analyses will be performed at Scandinavian Development Services AB (SDS), Danderyd, Sweden using SAS® (Version 9.3 or higher, SAS Institute Inc., Cary, NC, USA).

Continuous variables will be summarized using descriptive statistics (n, mean, SD, min, Q1, median, Q3, max). Categorical variables will be summarized in frequency tables (frequency and proportion). Graphical presentations, e.g. describing the change over time, will be used as appropriate, and individual patient data will be listed.

The primary and secondary endpoints (change in DLQI, Patient's Global Assessment of Skin Pain (NRS), HSIA, HiSCR, EQ5D, WPAI:SHP at 4, 12 and 24 weeks) will be analyzed using t-test or non-parametric methods such as Wilcoxon signed rank test as appropriate. The change at 12 weeks will be of primary interest.

No adjustment for multiple comparisons will be made.

A more detailed Statistical Analysis Plan (SAP) will be written and finalized before database lock.

Has been changed to read:

All statistical analyses will be performed at Scandinavian Development Services AB (SDS), Danderyd, Sweden using SAS® (Version 9.3 or higher, SAS Institute Inc., Cary, NC, USA).

Continuous variables will be summarized using descriptive statistics (n, mean, SD, min, Q1, median, Q3, max). Categorical variables will be summarized in frequency tables (frequency and proportion). Graphical presentations, e.g. describing the change over time, will be used as appropriate, and individual patient data will be listed.

The primary and secondary endpoints (change in DLQI, Patient's Global Assessment of Skin Pain (NRS), HSIA, HiSCR, EQ5D, WPAI:SHP at 4, 12 and 24 weeks) will be analyzed using t-test or non-parametric methods such as Wilcoxon signed rank test as appropriate. The change at 12 weeks will be of primary interest.

No adjustment for multiple comparisons will be made.

An interim analysis is planned to be performed during Q2 2017. No formal statistical tests will be performed on the interim data.

A more detailed Statistical Analysis Plan (SAP) will be written and finalized before interim database lock and final database lock.

Section Appendix 6, Administrative Change 1 – Summary of Changes

Previously read:

[none]

Has been changed to read:

Appendix 6 Administrative Change 1 - Summary of Changes

The purpose of the Administrative Change, dated 26 May 2016, was to:

- Update the protocol to reflect that paper CRF, and not eCRF, is used in the study.
- Update the protocol to reflect that Pharmacovigilance will no longer receive SAE reports via faxing.
- Correct typos.

Section Signature Page

Previously read:

AbbVie Inc. (AbbVie)

Post Marketing Observational Study

Protocol (P15-692)

Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 months on Adalimumab Treatment (HOPE study)

Approved by:

Protocol Author – [redacted]	Date
Protocol Author – [redacted]	Date
Study-Designated Physician – [redacted]	Date
Statistics Representative – [redacted], Scandinavian Development Services	Date
Project Director – [redacted]	Date

Has been changed to read:

AbbVie Inc. (AbbVie)

Post Marketing Observational Study

Protocol (P15-692)

Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 months on Adalimumab Treatment (HOPE study)

Approved by:

Protocol Author – [redacted]	Date
Protocol Author/Therapeutic Area Medical Director – [redacted]	Date
Statistics Representative – [redacted], Scandinavian Development Services	Date
Project Director – [redacted]	Date

Acknowledgment of the Principal Investigator:

1. I have read this Administrative Change to the protocol and agree that the study is ethical.
2. I agree to conduct the study as outlined and in accordance with all applicable regulations and guidelines.
3. I agree to maintain the confidentiality of all information received or developed in connection with this protocol.

Protocol Title:	Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 Months on Adalimumab Treatment (HOPE study)
Amendment Date:	07 February 2017

Signature of Principal Investigator _____ Date _____

Name of Principal Investigator (printed or typed) _____

Title Page

Title	Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 Months on Adalimumab Treatment (HOPE study)
Protocol Version Identifier	Version 1.0
Date of Last Version of Protocol	28 October 2015
Marketing Authorisation Holder(s)	AbbVie
Research Question and Objectives	The objective of this PMOS is to provide national data on Quality of Life changes in Swedish patients with moderate and severe HS treated with adalimumab as per standard clinical care.
Country(-ies) of Study	Sweden
Authors	[redacted], AbbVie AB [redacted] Affiliate Research, AbbVie AB

This study will be conducted in compliance with this protocol.

Confidential Information

No use or disclosure outside AbbVie is permitted without prior written authorization from AbbVie.

Marketing Authorisation Holder(s)

Marketing Authorisation Holder(s)	AbbVie AB Box 1523 S-171 29 Solna Sweden

1.0 Table of Contents

2.0 Abbreviations

AE	Adverse Event
BMI	Body Mass Index
CRF	Case Report Form
DLQI	Dermatology Life Quality Index
EQ	EuroQol
GCP	Good Clinical Practice
HiSCR	Hidradenitis Suppurativa Clinical Response
HS	Hidradentis Suppurativa
HSIA	Hidradenitis Suppurativa Impact Assessment
IEC	Independent Ethics Committee
NRS	Numerical Rating Scale
PCG	Pharma Consulting Group
QoL	Quality of Life
SAE	Serious Adverse Event
SDP	Study Designated Physician
SmPC	Summary of Product Characteristics
TNF	Tumor Necrosis Factor
WPAI:SHP	Work Productivity and Activity Impairment Questionnaire: Specific Health Problem

3.0 Responsible Parties

Contact details and a list of investigators will be kept at AbbVie and will be available upon request.

4.0 Abstract

Title: Post Marketing Observational Study to Assess Quality of Life Changes in Swedish Patients with Moderate or Severe Hidradenitis Suppurativa after 6 Months on Adalimumab Treatment (HOPE study)
Rationale and Background: HS has a huge impact on the patients' Quality of Life. Compared to other dermatological diseases (e.g. acne psoriasis, atopic eczema and skin tumors) the impact, measured by the Dermatology Life Quality Index (DLQI), is significantly greater. Although this is shown in studies from different parts of the world there is only limited information available on the Quality of Life in Swedish HS patients and there are no national registries capturing this information.
Research Question and Objectives: The objective of this observational study is to assess QoL, skin pain, work productivity/activity and health related problems in Swedish patients with moderate to severe HS before and after 6 months treatment with Adalimumab. The patients will be treated in accordance with normal routine clinical care.
Study Design: Post Marketing Observational Study (PMOS)
Population: Adult patients with a diagnosis of Hidradentis Suppurativa. The patients will be treated in accordance with normal routine care and the drug will be prescribed in accordance with the approved labeling (Summary of Product Characteristics).
Variables: • Demographic/baseline data • Dermatology Life Quality Index (DLQI) • EuroQol (EQ-5D) • Patient's Global Assessment of Skin Pain (NRS) • Hidradenitis Suppurativa Impact Assessment (HSIA) • Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP) • Hidradenitis Suppurativa Clinical Response (HiSCR)

• Serious Adverse Events
Data Sources: Data will be collected from the patient's medical records, by investigator assessment and by patient questionnaires. Electronic Case Report Forms (eCRF) will be used for each patient enrolled in this study. These forms will be used to transmit information collected during the study to AbbVie.
Study Size: n=50
Data Analysis: Continuous variables will be summarized using descriptive statistics (n, mean, SD, min, Q1, median, Q3, max). Categorical variables will be summarized in frequency tables (frequency and proportion). Graphical presentations, e.g. describing the change over time, will be used as appropriate, and individual patient data will be listed. The primary and secondary endpoints (change in DLQI, Patient's Global Assessment of Skin Pain (NRS), HSIA, HiSCR, EQ5D, WPAI:SHP at 4, 12 and 24 weeks) will be analyzed using t-test or non-parametric methods such as Wilcoxon signed rank test as appropriate
Milestones: Start of data collection: Planned Q1 2016 End of data collection: Planned Q3 2017 Final Report of Study Results: Planned Q3 2018

5.0 Amendments and Updates

None

6.0 Milestones

Major study milestones and their planned dates are as follows:

Start of Data Collection:	Planned Q1 2016
End of Data Collection:	Planned Q3 2017
Final Report of Study Results:	Planned Q3 2018

7.0 Background and Rationale

7.1 Hidradenitis Suppurativa

Hidradenitis Suppurativa (HS) also known as acne inversa, is a painful, chronic, skin disease characterized by recurrent inflamed nodules and abscesses, which may rupture to form fistulas and subsequent scarring. The most commonly involved anatomic locations are the axillary and sub-mammary folds, the inguino-crural, the gluteal and perineal areas.

HS has a severely negative effect on patients quality of life.[1,2] It typically presents with painful, deep-seated nodules, which either resolve spontaneously, persist as non-tender nodules, or progress to form abscesses. Abscesses typically rupture and release purulent drainage. Abscesses and nodules may heal with scarring and the formation of fistulas or sinus tracts. Thus, many patients with HS develop permanent sequelae of past inflammation that are only remediable through surgical excision of the involved skin areas. The physical and psycho-social morbidity associated with en bloc excision of scarred axillary, inguinal, or groin skin is substantial. Rare complications of HS include fistula formation into urethra, bladder, rectum, or peritoneum, lymphedema of the limbs or scrotal elephantiasis, and squamous cell carcinomas of the skin originating from HS lesions.

HS affects approximately 1 % of the general population. [3,4] Disease onset is typically after puberty. Disease prevalence decreases from 1.5% in those <25 years of age to 0.5% in those older than 55 years of age. It affects women from 2 to 5 times more commonly than men. Several factors may predispose a person to HS, including genetics, cigarette smoking, and obesity.[5]

HS is a clinical diagnosis; there are no specific laboratory testing or histopathological features. The severity is often classified according to Hurley. [6]

- Stage I: Abscess formation, single or multiple, without sinus tracts and cicatrisation.
- Stage II: Recurrent abscesses with tract formation and cicatrisation, single or multiple, widely separated lesions.
- Stage III: Diffuse or near-diffuse involvement, or multiple interconnected tracts and abscesses across the entire area.

Stage I disease occurs in 68% of patients, stage II in 28% of patients, while 4% of HS patients have stage III.[7]

7.2 Treatments

7.2.1 Current treatments

Adalimumab is the first pharmaceutical product approved for the treatment of HS and no treatment guidelines have been published after the approval. As with other dermatological diseases with only a few, or no approved medications, the treatment of HS, has mainly been based on trial and error, clinical experience, case reports/series and small RCTs.

According to the European S1 HS Guidelines, published in April 2015, HS treatment should be based on the individual subjective impact and the objective severity Hurley staging is recommended to be used as basis for the treatment algorithm.

Classic surgery or LASER surgery may be used on milder forms with local HS lesions while medical treatment, possibly in combination with radical surgery, is recommended for moderate to severe cases with widespread lesions. Medical treatment may include topical antibiotics (topical clindamycin) or systemic antibiotics, either as monotherapy (tetracyclin or clindamycin) or as a combination of two antibiotics (clindamycin and rifampicin). Acitretin and biologics are also included in the Guidelines as possible medical treatments. Adjuvant treatment, such as appropriate dressings, pain control, weight loss and tobacco abstinence should also be considered according to the clinical condition and need.[8]

7.2.2 Adalimumab

Case reports and series have shown that inhibitors of Tumor Necrosis Factor (TNF-α) are effective in treating HS.[9-11] Based on these observations, the investigation of Adalimumab, a fully human anti-TNF monoclonal antibody, for the treatment of moderate to severe HS was considered warranted.

The safety and efficacy of Adalimumab were assessed in randomised, double-blind, placebo-controlled studies and an open-label extension study in adult patients with

moderate to severe HS who were intolerant, had a contraindication or an inadequate response to at least a 3-month trial of systemic antibiotic therapy. The patients in HS-I and HS-II had Hurley Stage II or III disease with at least 3 abscesses or inflammatory nodules.

Study HS-I (PIONEER I)[12] evaluated 307 patients with 2 treatment periods. In Period A, patients received placebo or Adalimumab at an initial dose of 160 mg at Week 0, 80 mg at Week 2, and 40 mg every week starting at Week 4 to Week 11. Concomitant antibiotic use was not allowed during the study. After 12 weeks of therapy, patients who had received Adalimumab in Period A were re-randomised in Period B to 1 of 3 treatment groups (Adalimumab 40 mg every week, Adalimumab 40 mg every other week, or placebo from Week 12 to Week 35). Patients who had been randomised to placebo in Period A were assigned to receive Adalimumab 40 mg every week in Period B.

Study HS-II (PIONEER II)[13] evaluated 326 patients with 2 treatment periods. In Period A, patients received placebo or Adalimumab at an initial dose of 160 mg at Week 0 and 80 mg at Week 2 and 40 mg every week starting at Week 4 to Week 11. 19.3% of patients had continued baseline oral antibiotic therapy during the study. After 12 weeks of therapy, patients who had received Adalimumab in Period A were re-randomised in Period B to 1 of 3 treatment groups (Adalimumab 40 mg every week, Adalimumab 40 mg every other week, or placebo from Week 12 to Week 35). Patients who had been randomised to placebo in Period A were assigned to receive placebo in Period B.

Patients participating in Studies HS-I and HS-II were eligible to enrol into an open-label extension study in which Adalimumab 40mg was administered every week. Throughout all 3 studies patients used topical antiseptic wash daily.

Clinical Response:

Reduction of inflammatory lesions and prevention of worsening of abscesses and draining fistulas was assessed using Hidradenitis Suppurativa Clinical Response (HiSCR; 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count relative to Baseline). Reduction in HS-related skin pain was assessed using a Numeric Rating Scale in patients who entered the study with an initial baseline score of 3 or greater on a 11 point scale.

At Week 12, a significantly higher proportion of patients treated with Adalimumab versus placebo achieved HiSCR. At Week 12, a significantly higher proportion of patients in Study HS-II experienced a clinically relevant decrease in HS-related skin pain (see Table

16). Patients treated with Adalimumab had significantly reduced risk of disease flare during the initial 12 weeks of treatment.

Table 16: Efficacy Results at 12 Weeks, HS Studies I and II

	HS Study 1 (PIONEER I)		HS Study 2 (PIONEER II)	
	Placebo	Adalimumab 40mg Weekly	Placebo	Adalimumab 40mg Weekly
Hidradenitis Suppurativa Clinical Response (HiSCR)[a]	n = 154 40 (26.0%)	n = 153 64 (41.8%)*	n = 163 45 (27.6%)	n = 163 96 (58.9%)***
≥30% Reduction in Skin Pain[b]	n = 109 27 (24.8%)	n = 122 34 (27.9%)*	n = 111 23 (20.7%)	n = 105 48 (45.7%)***

* P < 0.05, ***P < 0.001, Adalimumab versus placebo

a. Among all randomised patients.
b. Among patients with baseline HS-related skin pain assessment ≥ 3, based on Numeric Rating Scale 0 – 10; 0 = no skin pain, 10 = skin pain as bad as you can imagine.

Among patients who were randomised to Adalimumab continuous weekly dosing, the overall HiSCR rate at Week 12 was maintained through Week 48.

Greater improvements at Week 12 from baseline compared to placebo were demonstrated in skin-specific health-related quality of life, as measured by the Dermatology Life Quality Index (DLQI; Studies HS-I and HS-II), patient global satisfaction with medication treatment as measured by the Treatment Satisfaction Questionnaire - medication (TSQM; Studies HS-I and HS-II), and physical health as measured by the physical component summary score of the SF-36 (Study HS-I).

Marketing authorization:

Adalimumab has recently received marketing authorization in EU as the first pharmaceutical product approved for the treatment of HS and is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

In addition to HS Adalimumab is approved for several other indications, e.g. rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, juvenile idiopathic arthritis, psoriasis, pediatric psoriasis, Crohn's disease, pediatric Chron's disease and ulcerative colitis.

7.3 Rationale

HS has a huge impact on the patients' Quality of Life. Compared to other dermatological diseases (e.g. acne psoriasis, atopic eczema and skin tumors) the impact, measured by the Dermatology Life Quality Index (DLQI), is significantly greater [14-18]. Although this is shown in studies from different parts of the world there is only limited information available on the Quality of Life in Swedish HS patients.

Results from the phase 3 studies of Adalimumab treatment in patients with moderate to severe HS, show significant clinical response, including improvement of QoL, reduction of pain and activity impairment after 12 weeks treatment.[12,13]

National data on the impact of HS on QoL, pain, work productivity and activity before and after Adalimumab treatment might be needed to support reimbursement in this indication. To date there are no national registries capturing this information. There is also a need to evaluate Adalimumab treatment for a longer period of time than 12 weeks in Swedish HS patients in whom conventional treatment has failed. Besides, CO_2 laser is rather commonly used in dermatological clinical practise in Swedish HS patients, for excision/incision of local HS lesions as well as for more widespread lesions.

Hence, national data on Adalimumab treatment of Swedish HS patients in a clinical dermatological setting might be needed in order to support reimbursement but also to support the development of an updated HS treatment algorithm.

8.0 Research Question and Objectives

The objectives of this observational study is to assess the changes in QoL, skin pain, work productivity/activity and health related problems before and after 6 months treatment with Adalimumab of Swedish patients with moderate to severe HS in real-life and as per routine clinical care.

Primary endpoints:

- Changes in Dermatology Life Quality Index (DLQI) at 12 weeks

Secondary endpoints:

- Change in DLQI at 4 and 24 weeks
- Change in Patient's Global Assessment of Skin Pain (NRS) at 4, 12 and 24 weeks
- Change in EuroQol (EQ-5D) at 4, 12 and 24 weeks
- Change in Hidradenitis Suppurativa Impact Assessment (HSIA) at 4, 12 and 24 weeks.
- Change in Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP) at 4, 12 and 24 weeks
- Hidradenitis Suppurativa Clinical Response (HiSCR) at 4, 12 and 24 weeks

9.0 Research Methods

9.1 Study Design

This is a Post Marketing Observational Study (PMOS), an open, non-interventional study. The patients will be treated in accordance with normal routine care and the drug will be prescribed in accordance with the approved labeling (Summary of Product Characteristics), i.e. AbbVie will not be involved in the supply of Adalimumab.

Patients will be included in the study at the time the physician has decided to change their current treatment to Adalimumab for any reason. The decision to prescribe adalimumab should be clearly separated from and preceding the decision to include the patient in the study. The patients will be assessed during routine visits at the clinic at baseline (inclusion) and after approximately 4 weeks, 12 weeks and 24 weeks. Data will be collected from the patient's medical records, by investigator assessment and by patient questionnaires as described in section 9.1.1 Study Flow Chart and in Section 9.3 Variables.

9.1.1 Study Flow Chart

Patients that have been prescribed Adalimumab as per routine care will asked to participate in this study. In accordance with routine care, a patient will be seen by the patient's physician at baseline (inclusion) and approximately 4, 12 and 24 weeks after the first dose of Adalimumab.

Parameters	**Baseline**	**Week 4**	**Week 12**	**Week 24**
Informed consent	X			
Demographic/baseline data	X			
Dermatology Life Quality Index (DLQI)	X	X	X	X
EuroQol (EQ-5D)	X	X	X	X
Patient's Global Assessment of Skin Pain (NRS)	X	X	X	X
Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP)	X	X	X	X
Hidradenitis Suppurativa Impact Assessment (HSIA)	X	X	X	X
Hidradenitis Suppurativa Clinical Response (HiSCR)	X	X	X	X
Serious Adverse Event		X	X	X
Pregnancy Reporting		X	X	X
Concomitant Medication	X	X	X	X
Surgical Treatment	X	X	X	X
Missed Adalimumab doses		X	X	X

9.2 Setting

Patients that have been prescribed Adalimumab as per routine care will be asked to participate in this study that will focus on their QoL, skin pain and work productivity/activity during a six month period.

The participating investigators will be dermatologists that routinely see HS patients. Approximately 10-20 clinics in Sweden will participate in the study.

Data will be collected at baseline and approximately 4, 12 and 24 weeks after the first dose of Adalimumab. Patients will be treated in in accordance with routine care.

9.2.1 Inclusion criteria

- Adult (18 years and older)
- Diagnosis of Hidradentis Suppurativa
- Prescribed Adalimumab according to the Summary of Product Characteristics (SmPC)
- Willingness to sign and date a Patient Information/Informed Consent Form

9.2.2 Exclusion criteria

- Prior biologic treatment discontinued <6 months before the baseline visit
- Patient not able to understand the language of the provided patient questionnaires
- History of non-compliance with medication or a medical history that could enhance non-compliance with medication, as determined by the investigator

9.3 Variables

9.3.1 Demographic/baseline data

The following data will be collected at the baseline visit:

- Demographic/Baseline data
    - Age, gender and ethnicity
    - Smoking habits
    - Body Mass Index (BMI)
    - Age when HS symptoms started
    - Date of diagnosis
    - HS assessment (lesion count and Hurley stage)

- Adalimumab treatment start (info on missed doses will be collected at 4, 12 and 24 weeks)
- Previous treatment(s) for HS
- Previous surgery for HS (info on new surgeries for HS will be collected at 4, 12 and 24 weeks)
- Co-morbidities

- Concomitant medications (changes in Concomitant Medication will be collected at 4, 12 and 24 weeks)

9.3.2 Quality of Life Scales

Three QoL scales will be completed at baseline and at 4, 12 and 24 weeks.

- The Dermatology Life Quality Index (DLQI) is a simple 10-question validated dermatologic disease questionnaire
- The EuroQol (EQ-5D) is a five dimensions generic questionnaire used to measure health-related QoL
- The Hidradenitis Suppurativa Impact Assessment (HSIA) is a disease specific questionnaire measuring the impact the patient experiences associated with HS.

9.3.3 Skin Pain

The Patient's Global Assessment of Skin Pain - numerical rating scale (NRS) will be completed at baseline and at 4, 12 and 24 weeks. Pain will be rated from 0 (no skin pain) to 10 (skin pain as bad as you can imagine).

9.3.4 Work Productivity

The Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP) measures the work productivity and activity impairment, will be completed by the patients at baseline and at 4, 12 and 24 weeks.

9.3.5 Clinical Effectiveness

HiSCR is a clinical endpoint focusing on assessment of HS inflammatory signs and symptoms that will determine the clinical effectiveness of Adalimumab.

Assessment will be performed by the physician at baseline and at 4, 12 and 24 weeks. HiSCR requires:

- At least a 50% reduction in the total abscess and inflammatory nodule count (AN count) relative to baseline, and
- No increase in abscess count, and
- No increase in draining fistula count.

9.3.6 Safety Parameters

Please see section 11.0

9.4 Data Sources

Data will be collected from the patient's medical records, by investigator assessment and by patient questionnaires as described in section 9.1.1 Study Flow Chart and in Section 9.3 Variables.

Electronic Case Report Forms (eCRF) will be used for each patient enrolled in this study. These forms will be used to transmit information collected during the study to AbbVie

9.5 Study Size

With 50 evaluable patients, the power is 90% based on a change in DLQI of -5.4, and an assumed standard deviation of 11.5 and type I error of 5% (two-sided). The drop-out rate is considered to be low, approximately 5% after 12 weeks, which will have a minimal impact on the power (decreased to 88%).

9.6 Data Management

Source documents are defined as original documents, data and records. This may include hospital records, clinical and office charts, laboratory data/information and patients' questionnaires. Data collected during this study must be recorded on the appropriate source documents.

The following assessments that will be completed by the patients or physician will be considered source documentation:

- DLQI
- EQ-5D
- HSIA
- Patient's Global Assessment of Skin Pain (NRS)
- WPAI:SHP
- HiSCR

Electronic Case Report Forms (eCRF) must be completed for each patient enrolled in this study. These forms will be used to transmit information collected during the study to AbbVie.

The eCRF data for this study are being collected in a system called VieDoc® provided by the technology vendor Pharma Consulting Group, PCG.

The investigator will document patient data in his/her own patient files. These patient files will serve as source data for the study. Investigative site personnel will record all eCRF data required by this protocol in the eCRF system.

The investigator or an authorized member of the investigator's staff will make any necessary corrections to the eCRF. All change information, including the date and person

performing the corrections, will be available via the audit trail, which is part of the system.

For any correction, a reason for the alteration will be provided. The eCRFs will be reviewed periodically for completeness, legibility, and acceptability by AbbVie personnel (or their representatives). As applicable, AbbVie (or their representatives) will also be allowed access to all source documents pertinent to the study in order to verify eCRF entries. The Principal Investigator will review the eCRFs for completeness and accuracy and provide his or her electronic signature and date to eCRFs as evidence thereof.

PCG will provide access to the eCRF for the duration of the trial through a password-protected method of Internet access. Such access will be removed from investigator sites at the end of the site's participation in the study. Data from the eCRF system will be archived on appropriate data media (CD-ROM, etc.) and provided to the investigator at that time as a durable record of the site's eCRF data. It will be possible for the investigator to make paper printouts from that media.

9.7 Data Analysis

All statistical analyses will be performed at Scandinavian Development Services AB (SDS), Danderyd, Sweden using SAS® (Version 9.3 or higher, SAS Institute Inc., Cary, NC, USA).

Continuous variables will be summarized using descriptive statistics (n, mean, SD, min, Q1, median, Q3, max). Categorical variables will be summarized in frequency tables (frequency and proportion). Graphical presentations, e.g. describing the change over time, will be used as appropriate, and individual patient data will be listed.

The primary and secondary endpoints (change in DLQI, Patient's Global Assessment of Skin Pain (NRS), HSIA, HiSCR, EQ5D, WPAI:SHP at 4, 12 and 24 weeks) will be analyzed using t-test or non-parametric methods such as Wilcoxon signed rank test as appropriate. The change at 12 weeks will be of primary interest.

No adjustment for multiple comparisons will be made.

A more detailed Statistical Analysis Plan (SAP) will be written and finalized before database lock.

9.8 Quality Control

An investigator's meeting and/or study initiation visit will be organized by AbbVie personnel in order to train the investigator(s) and study coordinator(s) on the protocol, eCRF procedures and other study procedures.

The study will be monitored in accordance with the pre-defined Monitoring Plan. Source document review will be performed against entries in the eCRF database as applicable and a quality assurance check will be performed.

Computer logic and manual checks will be run to identify items such as inconsistent study dates. Any necessary corrections will be made to the eCRF.

A Study Designated Physician (SDP) at AbbVie will conduct a review of all collected Serious Adverse Events and spontaneously reported Adverse Events.

9.9 Limitations of the Research Methods

This is a Post Marketing Observational Study in which the outcome of the treatment will be compared to the baseline data for each individual patient, i.e. no control groups exist in the study.

9.10 Other Aspects

N/A

10.0 Protection of Human Subjects

10.1 Ethical Conduct of the Study

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, the protocol, Good Clinical Practice (GCP) as applicable and applicable Swedish regulations.

10.2 Independent Ethics Committee (IEC)

Good Clinical Practice (GCP) requires that the clinical protocol, any protocol amendments, the informed consent and all other forms of patient information related to the study (e.g., advertisements used to recruit subjects) and any other necessary documents be reviewed by an IEC. The IEC will review the ethical, scientific and medical appropriateness of the study before it is conducted. IEC/IRB approval of the protocol, informed consent and patient information and/or advertising, as relevant, will be obtained prior to the start of any study procedure.

Any amendments to the protocol will require IEC approval prior to implementation of any changes made to the study design. The investigator will be required to submit, maintain and archive study essential documents according to GCP.

Any Serious Adverse Events that meet the reporting criteria, as dictated by local regulations, will be reported to the Regulatory Agencies, as required by local regulations.

10.3 Patient Information and Consent

The investigator or his/her representative will explain the nature of the study to the patient, and answer all questions regarding this study. Prior to any study-related procedures being performed on the patient, the informed consent statement will be reviewed and signed and dated by the patient, the person who administered the informed consent, and any other signatories according to local requirements.

A copy of the informed consent form will be given to the patient. An entry must also be made in the patient's source documents to confirm that informed consent was obtained prior to any study-related procedures and that the patiemt received a signed copy.

11.0 Management and Reporting of Complaints

A Complaint is any written, electronic, or oral communication that alleges deficiencies related to the physical characteristics, identity, quality, purity, potency, durability, reliability, safety, effectiveness, or performance of a product/device after it is released for distribution.

The investigational product in this trial contains both:

- Biologic compound(s) and
- Device component(s) (pre-filled syringe, pen).

Complaints associated with any component of this investigational product must be reported to the Sponsor (Section 11.2.2). For adverse events, please refer to Sections 11.1.1 through 11.1.6. For product complaints, please refer to Section 11.2.

11.1 Medical Complaints

11.1.1 Adverse Event Definition and Serious Adverse Event Categories

An adverse event (AE) is defined as any untoward medical occurrence in a patient, which does not necessarily have a causal relationship with their treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not the event is considered causally related to the use of the product.

Such an event can result from use of the drug as stipulated in the labeling, as well as from accidental or intentional overdose, drug abuse, or drug withdrawal. Any worsening of a pre-existing condition or illness is considered an adverse event.

If an adverse event meets any of the following criteria, it is considered a serious adverse event (SAE):

Death of Patient:	An event that results in the death of a patient.
Life-Threatening:	An event that, in the opinion of the investigator, would have resulted in immediate fatality if medical intervention had not been taken. This does not include an event that would have been fatal if it had occurred in a more severe form.
Hospitalization:	An event that results in an admission to the hospital for any length of time. This does not include an emergency room visit or admission to an outpatient facility.

Prolongation of Hospitalization:	An event that occurs while the study patient is hospitalized and prolongs the patient's hospital stay.
Congenital Anomaly:	An anomaly detected at or after birth, or any anomaly that results in fetal loss.
Persistent or Significant Disability/Incapacity:	An event that results in a condition that substantially interferes with the activities of daily living of a study patient. Disability is not intended to include experiences of relatively minor medical significance such as headache, nausea, vomiting, diarrhea, influenza, and accidental trauma (e.g., sprained ankle).
Important Medical Event Requiring Medical or Surgical Intervention to Prevent Serious Outcome:	An important medical event that may not be immediately life-threatening or result in death or hospitalization, but based on medical judgment may jeopardize the patient and may require medical or surgical intervention to prevent any of the outcomes listed above (i.e., death of patient, life threatening, hospitalization, prolongation of hospitalization, congenital anomaly, or persistent or significant disability/incapacity). Additionally, any elective or spontaneous abortion or stillbirth is considered an important medical event. Examples of such events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

11.1.2 Severity

The following definitions will be used to rate the severity for any adverse event being collected as an endpoint/data point in the study and for all serious adverse events.

Mild:	The adverse event is transient and easily tolerated by the patient.

Moderate:	The adverse event causes the patient discomfort and interrupts the patient's usual activities.
Severe:	The adverse event causes considerable interference with the patient's usual activities and may be incapacitating or life threatening.

11.1.3 Relationship to Pharmaceutical Product

The following definitions will be used to assess the relationship of the adverse event to the use of product:

Reasonable Possibility	An adverse event where there is evidence to suggest a causal relationship between the product and the adverse event.
No Reasonable Possibility	An adverse event where there is no evidence to suggest a causal relationship between the product and the adverse event.

If no reasonable possibility of being related to product is given, an alternate etiology must be provided for the adverse event.

11.1.4 Serious Adverse Event Collection Period

Serious adverse events will be reported to AbbVie from the time the physician obtains the patient's authorization to use and disclose information (or the patient's informed consent) until 30 days or 5 half-lives following the intake of the last dose of physician-prescribed treatment.

11.1.5 Serious Adverse Event Reporting

In the event of a serious adverse event, and additionally, any non-serious event of malignancy in patients 30 years of age and younger, whether related to study drug or not, the Investigator will notify the AbbVie contact identified in section 11.1.5 within 24 hours of the site being made aware of the event by entering the serious adverse event or non-serious event of malignancy in patients 30 years of age and younger data into the electronic data capture (EDC) system. Serious adverse events and non-serious events of malignancy in patients 30 years of age and younger, that occur prior to the site having

access to the EDC system or if the EDC system is not operable should be faxed/e-mailed to the AbbVie contact identified in section 11.1.5 within 24 hours of being made aware of the adverse event.

In the event of a serious adverse event, the physician will:

- For events from patients using and AbbVie product - notify the AbbVie contact person identified below within 24 hours of the physician becoming aware of the event.
- For events from patients using a comparator product – notify the Marketing Application Holder (MAH) for the comparator product within 24 hours of the physician becoming aware of the event.

Contact details for event reporting:
E-mail: [redacted]
Phone: [redacted]
Fax: [redacted]

As the safety profile of Adalimumab is stable and well established, non-serious events will not be actively solicited as these events are not likely to further contribute to the understanding of the safety profile of the product. Any non-serious reports will be collected as spontaneous reports if notified to AbbVie.

11.1.6 Pregnancy Reporting

In the event of a pregnancy occurrence in the patient, the physician will notify AbbVie contact identified in Section 11.1.5 within 24 hours of the physician becoming aware of the pregnancy.

11.2 Product Complaint

11.2.1 Definition

A Product Complaint is any Complaint (see Section 11.0 for the definition) related to the biologic or drug component of the product or to the medical device component(s).

For a product this may include, but is not limited to, damaged/broken product or packaging, product appearance whose color/markings do not match the labeling, labeling discrepancies/inadequacies in the labeling/instructions (example: printing illegible), missing components/product, device not working properly, or packaging issues.

For medical devices, a product complaint also includes all deaths of a patient using the device, any illness, injury, or adverse event in the proximity of the device, an adverse event that could be a result of using the device, any event needing medical or surgical intervention including hospitalization while using the device and use errors.

Any information available to help in the determination of causality by the device to the events outlined directly above should be captured.

11.2.2 Reporting

Product Complaints concerning the investigational product and/or device must be reported to the Sponsor within 24 hours of the study site's knowledge of the event via local Product Complaint reporting practices. Product Complaints occurring during the study will be followed-up to a satisfactory conclusion. All follow-up information is to be reported to the Sponsor (or an authorized representative) and documented in source as required by the Sponsor. Product Complaints associated with adverse events will be reported in the study summary. All other complaints will be monitored on an ongoing basis.

Product complaints involving a non-Sponsor investigational product should be reported to the identified contact or manufacturer, as necessary per local regulations.

Product Complaints may require return of the product with the alleged complaint condition (syringe, pen, etc.). In instances where a return is requested, every effort should be made by the investigator to return the product within 30 days. If returns cannot be accommodated within 30 days, the site will need to provide justification and an estimated date of return.

The description of the complaint is important for AbbVie in order to enable AbbVie to investigate and determine if any corrective actions are required.

12.0 Plans for Disseminating and Communicating Study Results

Core publication(s) will be authored by Principal Investigator(s) specified by AbbVie who contribute significantly to the implementation and conduct of the study and non-site personnel who contribute substantially to the design, interpretation or analysis of the study (e.g., AbbVie personnel or consultants). AbbVie scientists making significant contributions to the study will be included in the list of authors.

Development of the core publication will be coordinated by a publication committee, whose membership will include investigators who provided significant input into study design, implementation, conduct and interpretation, in addition to AbbVie scientific personnel responsible for study conduct.

At the end of the study, AbbVie will write a study report. This report will contain a description of the objectives of the PMOS, the methodology of the study, its results and conclusions.

The completed case report forms, questionnaires and the study report are the confidential property of AbbVie and may not be released to unauthorized people in any form (publications or presentations) without express written approval from AbbVie.
The results of this PMOS may be published by AbbVie or by any one of the participating Investigators after agreement with AbbVie.

13.0 References

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Appendix 1. Dermatology Life Quality Index (DLQI) – Example

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please check √ one box for each question.

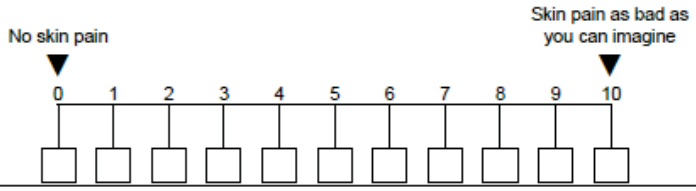
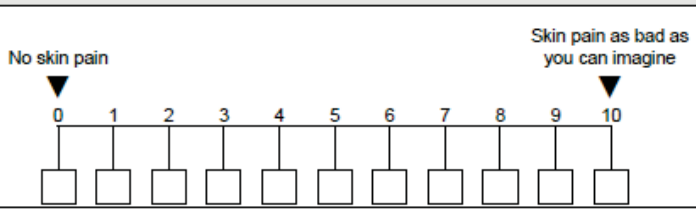
Question	Response	
1. Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	
2. Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	
3. Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **yard**?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
4. Over the last week, how much has your skin influenced the **clothes** you wear?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
5. Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
6. Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐

7. Over the last week, has your skin prevented you from **working** or **studying**? If "No", over the last week how much has your skin been a problem at **work** or **studying**?	yes ☐ no ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
8. Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
9. Over the last week, how much has your skin caused any **sexual difficulties**?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐
10. Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much ☐ A lot ☐ A little ☐ Not at all ☐	Not relevant ☐

Please check you have answered EVERY question. Thank you.

Appendix 2. Patient's Global Assessment of Skin Pain – NRS – Example

Please mark an "X" in the box (☒) which best describes the severity of your skin pain in the last 7 days.

1. In the last 7 days, which number best describes your skin pain at its worst due to your HS?	
2. In the last 7 days, which number best describes your skin pain on average due to your HS?	

Appendix 3 EuroQol (EQ-5D) – Example

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	☐
I have some problems in walking about	☐
I am confined to bed	☐

Self-Care

I have no problems with self-care	☐
I have some problems washing or dressing myself	☐
I am unable to wash or dress myself	☐

Usual Activities (*e.g., work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities	☐
I have some problems with performing my usual activities	☐
I am unable to perform my usual activities	☐

Pain/Discomfort

I have no pain or discomfort	☐
I have moderate pain or discomfort	☐
I have extreme pain or discomfort	☐

Anxiety/Depression

I am not anxious or depressed	☐
I am moderately anxious or depressed	☐
I am extremely anxious or depressed	☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

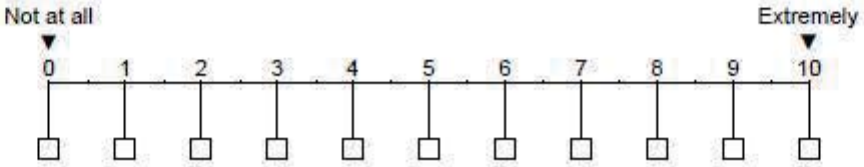
Your own health state today

Appendix 4 Hidradenitis Suppurativa Impact Assessment (HSIA) – Example

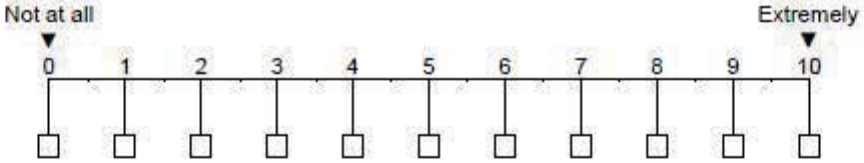
Instructions: This questionnaire includes 18 questions about the impacts that you may experience associated with your Hidradenitis Suppurativa (HS). Hidradenitis Suppurativa is a skin condition that affects areas with sweat glands such as the underarms, breasts, inner thighs, groin, and buttocks. People often refer to their HS as boils, cysts, or lesions on their skin.

Please clearly mark an "x" **in the box** (☒) that best describes how you have been affected by your **HS** in the **past 7 days.** There are no right or wrong answers to any of the questions.

1. Over the **past 7 days**, how uncomfortable did your clothing make you feel because of your HS?

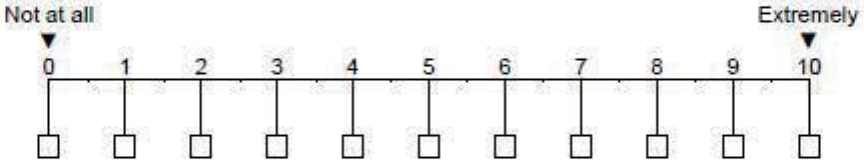


2. Over the **past 7 days**, how hard was it for you to move your arms because of your HS?



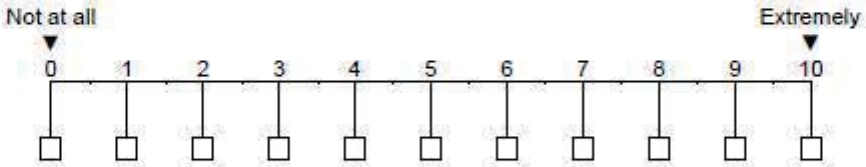
3. Over the **past 7 days**, how hard was it for you to exercise (for example, play sports, work out) because of your HS?

Note: If you **did not exercise** because of your HS please mark a "10".



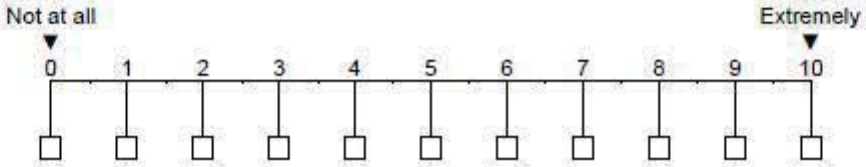
4. Over the **past 7 days**, how hard was it for you to walk because of your HS?

Note: If you **did not walk** because of your HS please mark a "10".

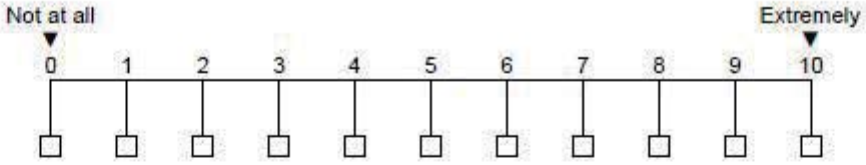


5. Over the **past 7 days**, how hard was it for you to sit because of your HS?

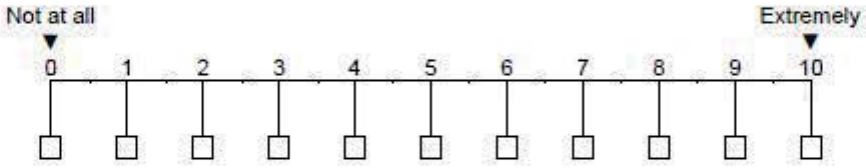
Note: If you **did not sit** down because of your HS please mark a "10".



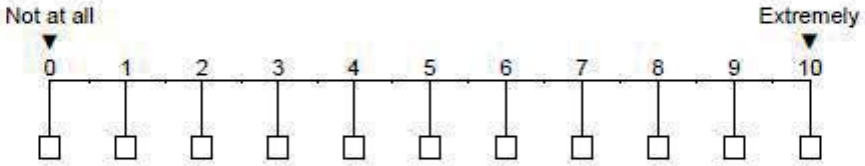
6. Over the **past 7 days**, how much did your HS interfere with your wanting to be around other people (for example, going to a party, being with friends or family)?



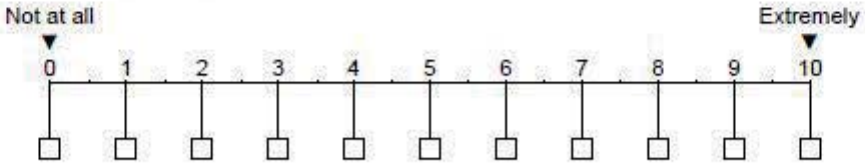
7. Over the **past 7 days**, how much did your HS interfere with your ability to do things around the house (for example, cleaning, cooking, yard work)?



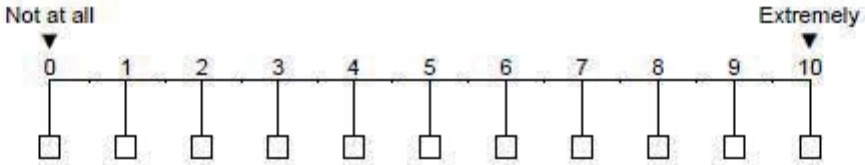
8. Over the past 7 days, how self-conscious did you feel because of your HS?



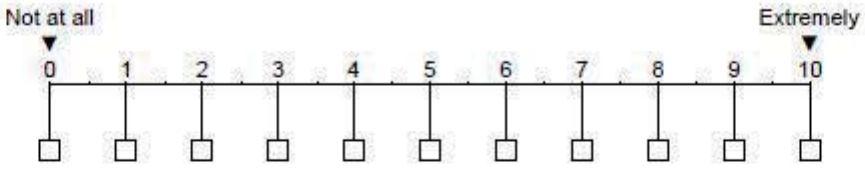
9. Over the **past 7 days**, how embarrassed did you feel because of your HS?



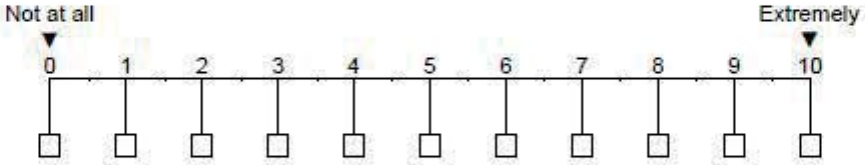
10. Over the **past 7 days**, how sad did you feel because of your HS?



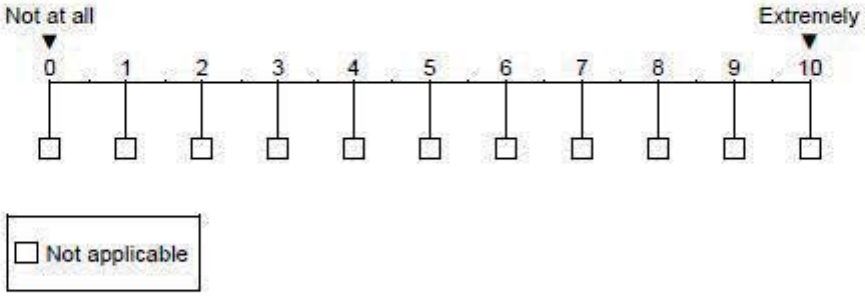
11. Over the **past 7 days**, how worried did you feel because of your HS?



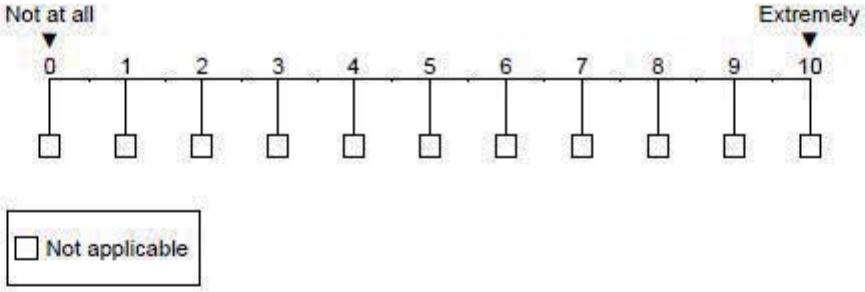
12. Over the **past 7 days**, how bothered did you feel because of your HS?



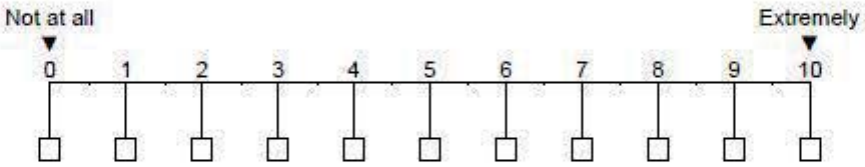
13. Over the **past 7 days**, how much did your feelings about your HS limit your desire to have sex (for example, because you felt unattractive, embarrassed, self-conscious, etc.)?



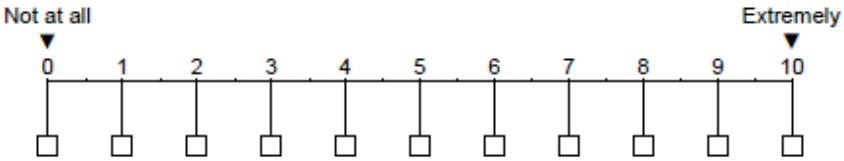
14. Over the **past 7 days**, how much was your ability to have sex limited because of your HS symptoms (for example, pain, cysts, drainage, flare ups, bleeding, etc.)?



15. Over the **past 7 days**, how satisfied have you been with your HS medications?



16. Over the past 7 days, how bothered did you feel by the scars from your past HS surgery/surgeries?



☐ Not applicable. I have not had surgery for my HS

17. Over the **past 7 days**, how many hours did you spend at work or school?

_____ Hours

☐ Not applicable. I am not employed nor do I attend school

18. Over the **past 7 days**, how many hours did you miss from work or school because of your HS? Include hours you missed on sick days, times you went in late, left early, etc., because of your HS.

_____ Hours

☐ Not applicable. I am not employed nor do I attend school

Appendix 5 Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP) - Example

The following questions ask about the effect of your hidradenitis suppurativa on your ability to work and perform regular activities. *Please fill in the blanks or circle a number, as indicated.*

1. Are you currently employed (working for pay)? _____ NO ___ YES

   If NO, check "NO" and skip to question 6.

The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems associated with your hidradenitis suppurativa? *Include hours you missed on sick days, times you went in late, left early, etc. because of your hidradenitis suppurativa. Do not include time you missed to participate in this study.*

   _____HOURS

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

   _____HOURS

4. During the past seven days, how many hours did you actually work?

   _____HOURS *(If "0," write "0" and skip to question 6.)*

5. During the past seven days, how much did hidradenitis suppurativa affect your productivity while you were working?

Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If hidradenitis suppurativa affected your work only a little, choose a low number. Choose a high number if hidradenitis suppurativa affected your work a great deal.

Hidradenitis suppurativa had no effect on my work	0	1	2	3	4	5	6	7	8	9	10	Hidradenitis suppurativa completely prevented me from working

CIRCLE A NUMBER

6. During the past seven days, how much did hidradenitis suppurativa affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, child care, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If hidradenitis suppurativa affected your activities only a little, choose a low number. Choose a high number if hidradenitis suppurativa affected your activities a great deal.

Hidradenitis suppurativa had no effect on my daily activities	0	1	2	3	4	5	6	7	8	9	10	Hidradenitis suppurativa completely prevented me from doing my daily activities

CIRCLE A NUMBER

WPAI:SHP (US English)